REMARKS

Specification Amendments

The statements of invention on pages 3, 4 and 8 have been amended for consistency with amended Claims 1 and 16 (*infra).*

No new matter has been introduced by the current or previous amendments to the specification.

Claim Amendments

In order to facilitate allowance, amendments have been made to Claims 1 and 16 in order to further distinguish over the prior art. However, it is submitted that, for reasons explained below, the (un)amended claims are neither anticipated by, nor obvious over, the prior art.

Claim 1 has been amended to require that the first and second feed gas supply inlets are in the higher pressure section and to specifically state that the concentration determining means measures concentration in the main circuit and that the flow control means and purification means are in the medical device supply circuit.

Claim 2 is redundant over amended Claim 1 and has been deleted.

Claim 16 has been amended for greater consistency with amended Claim 1.

New Claims 25 to 30 specify the identity of the medical gas mixture in the method of Claim 16 and have basis in Claims 18 to 23 respectively of the original (PCT) application. If the presence of one or more of the new claims is the only objection to allowance of the application, the Examiner has authority to delete the offending claim(s).

No new matter has been added by the current or previous claim amendments.

Re Examiner's Response to Arguments.

The Examiner has asserted that, contrary to the submissions made in the Response filed on June 2nd, 2010, the flow control valve **132** of Lampotang *et al* (US 6,131,571) is capable of acting as

a pressure maintaining valve dividing the main circuit into a higher pressure section and a lower pressure section as required of the apparatus of Claim 1. The valve is consistently described in Lampotang *et al* as a *proportional flow control valve*. Even if the proportional flow control valve **132** has the structure permitting it to perform that function in an appropriate circulation loop, this is not the case in Lampotang *et al*. It can be considered to divide the recirculation circuit **12** into a first section extending, in the flow direction, between the valve **132** and the pump **36** and a second section extending, in the flow direction, between the pump **36** and the valve **132**. However, the proportional flow control valve **132** is constructed and arranged to provide alternating back pressure and suction at the Y- piece **14** located upstream of the valve **132**. It is not possible to operate the apparatus of Lampotang *et al* with a constant pressure maintained in the circuit section upstream of the valve **132**.

The Examiner states that *Figure 2 of the Lampotang reference shows the spent gas inlet **14** in a different pressure section from the medical gas outlet*. The Applicant is unable to locate this *medical gas outlet*. In the apparatus of Lampotang *et al* Figure 2, the Y-piece **14** alternately performs the function of medical gas outlet from the recirculation circuit **12** and spent gas inlet into that circuit. The Y-piece **14** is at a fixed location in the recirculation circuit **12** and it is variation of pressure in that section that enables the Y-piece to perform the functions of both medical gas outlet and spent gas inlet.

As noted by the Examiner, it is stated in Lampotang *et al* at column 13, lines 33/35 that *The multi-gas analyzer **120** is capable of measuring concentrations of carbon dioxide, oxygen, nitrous oxide and volatile anesthetics*. However, this measurement is conducted at the distal tip **32** of the endotracheal tube **16** attached to the Y-piece (see column 13, lines 25/28) and according measures gas concentration in the patient's respiratory passageway and not gas concentration in the recirculating circuit. In this connection, it is specifically stated at column 13, lines 28/32 that:-

> *The sampling port 122 is placed at that location, because if gas concentrations were monitored at the Y-piece **14**, for example, or any other location around the circulation loop **12**, **measurements would be diluted by the recirculating flow of fresh gases**.* (emphasis added)

and at column 21, lines 4/9 that:-

> *As noted above, the sampling port **122** of the multi-gas analyzer **120** is located at the distal tip **32** of endotracheal tube **16**, near the carina **30** of the patient, thus enabling it to provide measurements of gas concentrations at the lungs **without the influence of gases circulating within the loop 12**.* (emphasis added)

It is not understood how the Examiner can conclude from column 16, lines 15/37 that one of the gas make-up valves **200 & 202** is responsive to a signal from the concentration determining means (multi-gas analyzer **120**) and the other is responsive to a signal from a circuit volume regulating means (bellows **216**). Control of these valves is discussed at column 17, line 36/46, stating that:-

> *If the bellows **212** fails to return to its baseline position at end exhalation, the linear optical encoder **228** sends a signal to the control **34** which opens valves **200, 202**. The proportional flow control valves **200, 202** are controlled to introduce fresh gas into the circuit **12** at a total flow rate proportional to the distance of the bottom of the bellows **212** from its baseline position, until eventually the bottom of the bellows **212** returns to such baseline position.*;

and at column 21, lines 11/14, stating that:-

> *Signals from the multi-gas analyzer **120** are provided to the controller **37** which includes PID control algorithms effective to control the operation of syringe pump **40**, and valves **200, 202**, such that they open and close to introduce the required amount of volatile anesthetic, oxygen and nitrous oxide, respectively, into the circulation loop **12**.*;

and at column 21, lines 38/43, stating that:-

> *The signals received by the controller **34** from the linear encoder **228** are representative of the distance of the bellows **212** from its bottom position, and fresh*

gas is introduced into the circuit ***12*** *from valves* ***200, 202*** *at a total flow rate proportional to such distance.*

There does not appear to be any disclosure in Lampotang *et al* that refers to gas make-up valve **200** being controlled in a different manner from gas make-up valve **202**, other than when only make-up valve **200** is operated to perform an oxygen flush of the recirculation circuit **12** (see column 16, lines 38/61).

The carbon dioxide absorbent canister **60** to which the Examiner refers is in the recirculation circuit not in *a medical device supply circuit* as required by present Claim 1. The claim requires that the latter circuit connects the medical device to the recirculating circuit to receive *medical gas* and return *spent gas*. In the apparatus of Lampotang *et al*, medical gas is supplied to and spent gas is returned from the patient by Y-piece **14** and there is no provision for purifying the spent gas before return to the recirculation circuit.

It is believed that it is clear from the wording and indentation at the end of present Claim 1 that both the medical gas flow control means and the spent gas purification means are in the medical device supply circuit but the claim has been amended to put the matter beyond any doubt.

Objection under 35 USC § 132(a)

With respect, the Examiner's assertion that the amendment filed on 2 June 2010 added matter to the specification is mistaken. There is clear and unambiguous basis for introduction of the wording *in order to maintain a constant pressure in the higher pressure section* at original (i.e. as in (WO 03/092776) page 4, lines 23 to 26 where it is stated that:-

Preferably, the pressure maintaining valve is a spill valve; i.e. a valve which opens wider in response to increased pressure to pass more gas into the lower pressure section and ***thereby maintain the pressure in the higher pressure section****. However, the valve could be a conventional pressure reduction valve.* (emphasis added)

Further, the method aspect of an invention stated at original page 8, lines 7/9 specified that the medical gas mixture recirculates *in a main circuit having* ***a higher pressure section maintained at constant pressure*** *in series with a lower pressure section.* (emphasis added)

Moreover, in the description of the exemplified embodiment of Figure 1, it is stated at original page 12, lines 20 to 23 that:-

> *Pressure maintaining valve* ***141*** *is a valve which allows gas to flow only when the pressure exceeds a predetermined level, for example 30 mbarg (103 kPa) and accordingly* ***maintains a constant pressure between the pumps 17 and the valve 141.*** (emphasis added)

It is respectfully maintained that the amendment filed on June 2nd, 2010 did not introduce any matter into the disclosure (or claims) that did not have clear and unambiguous support in the description as originally filed. Accordingly, there is no new matter that requires cancellation.

Claim Rejections under 35 USC § 112

With respect, the Examiner's assertion that Claims 1 to 6 and 9 to 14 fail to comply with the written description requirement is mistaken. As explained above, the feature of maintenance of a constant pressure in the higher pressure section is described in the specification and has been present since the application was filed.

Claim Rejections under 35 USC § 102

With respect, the Examiner's assertion that apparatus within the scope of Claims 1 and 3 to 6 and the method of Claim 16 are anticipated by Lampotang *et al* is mistaken. As discussed above in connection with the 35 USC § 132(a) objection, it is believed that the Examiner's response to the Applicant's arguments of June 2nd, 2010 is defective. Further, it is submitted that there are major inaccuracies in the Examiner's understanding of the teaching of Lampotang *et al* as set forth in #8 of the Detailed Action.

For reasons explained above, proportional flow control valve 132 of Lampotang *et al* does not divide the main circuit **12** into a higher pressure section and a lower pressure section and it does not maintain, and is not capable of maintaining, a constant pressure in the higher pressure section

of the Lampotang *et al* apparatus. It is irrelevant to the novelty of Claim 1 that the proportional flow control valve **132** might in other apparatus divide a recirculating gas circuit into a higher pressure section and a lower pressure section in order to maintain a constant pressure in the higher pressure section. What matters is the function that the proportional flow control valve **132** is capable of performing in the relevant apparatus. In this connection, valve **132** is not a conventional flow control valve but is a proportional flow control valve specially designed and controlled to provide pressure variations facilitating flow to and from an endotracheal tube **16** or face mask connected to the recirculating circuit **12** at Y-piece **14**. It is not certain that the valve is constructed or capable of control in a manner that would maintain a constant pressure in a (different) recirculating circuit and it appears that it is not a *spill valve* (as asserted by the Examiner in connection with Claim 3) because it appears that it does not open wider in response to increased pressure to allow more gas to pass through the valve.

For reasons explained above, Y-piece **14** cannot constitute both a medical gas outlet in one section of the recirculating circuit **12** and a spent gas inlet in another section of that circuit. It alternates between supply of medical gas from the recirculation circuit and return of spent gas to that circuit; it is the pressure in the circuit portion that varies and not the section to which the Y-piece is attached.

The gas make-up valves **200, 202** are located downstream of the Y-piece **14**, which does alternately function as a medical gas outlet but they are downstream, not upstream, of the proportional flow control valve **132**.

As explained above, the multi-gas analyzer **120** does not measure the concentration of a component of the recirculating medical gas mixture. It samples gas from a location specifically selected so that it analyzes gas in the patient and not in the recirculating circuit.

As explained above, there is no disclosure in Lampotang *et al* of controlling one feed gas supply in response to a signal from the multi-gas analyzer (which, in any event, does not measure concentration with gas in the recirculating circuit) and controlling a second feed gas supply in response to a signal from the bellows **216**.

The Y-piece **14** and endotracheal tube **16** do not constitute a medical device supply circuit in that medical gas and spent gas flow in alternate countercurrent direction to and from the patient's lung. Moreover, there is no provision in the Y-piece or endotracheal tube for controlling gas flow and no means for removing contaminants from the spent gas.

In connection with the above, the Examiner's attention is drawn to the International Search Report and International Preliminary Examination Report that issued in connection with the parent PCT application. Lampotang *et al* was cited in the International Search Report (identified as "Gravenscein Joachim S *et al*") under category Y (not X) and the International Preliminary Examination Report stated that the apparatus claims (Claims 1 to 15) were novel (implicitly over Lampotang *et al*). Claims 16 to 24 were not searched or examined in the International phase because they were considered to be formally unallowable (PCT) claims to methods of medical treatment,

Claims 3 to 6 and 9 to 14 are necessarily novel over Lampotang *et al* because they are dependent on Claim 1, which for the reasons explained above is clearly novel over Lampotang *et al*. Moreover, there is no teaching in Lampotang *et al* that proportional flow control valve **132** is a spill valve (see Claim 3); there is no teaching concerning relative flow rate increases of the make-up gases (see Claim 5); and the multi-gas analyzer **120** does not measure oxygen concentration in the recirculating circuit **12** (see Claim 6).

Claim 16 is distinguished over Lampotang *et al* for reasons corresponding to those discussed above in connection with Claim 1. The endotracheal tube **16** (or the alternative face mask) is not a medical device; the recirculating circuit **12** does not have a higher pressure section maintained at constant pressure in series with a lower pressure section; and contaminants are not removed from the spent gas mixture before return to the recirculating circuit.

Having regard to the above and the Examiner's comments concerning allowable subject matter (#23 of the Detailed Action), it is respectfully submitted that all of the present claims are clearly novel over Lampotang *et al*.

Claim Rejections under 35 USC § 103(a)

It is respectfully submitted that the present claims are patentable over the prior art and, in particular, that the claimed subject matter is not obvious over Lampotang *et al* whether considered alone or in view of any one or combination of Siemens (EP-A-0 745 405), Vladimirovna (EP-A- 0 861 372) and Dyachenko (SU-A-1 188 638). It appears that this rejection is predicated on the mistaken assertion that previous Claim 1 lacks novelty over Lampotang *et al*. The reasoning for the rejection of Claims 2 and 9 to 13 is clearly insufficient in the absence of reasoned argument as to why Claim 1 might be obvious over Lampotang *et al* (*arguendo).* However, this issue was addressed in the Applicant's Response of 2 June 2010 in reply to the 35 USC § 103(a) objection raised in the previous Office Action. For the Examiner's convenience, the relevant passage is reproduced below:-

> *It is respectfully submitted that the amended claims are patentable over the prior art and, in particular, that the claimed subject matter is not obvious over Lampotang et al whether considered alone or in view of anyone or combination of Siemens, Vladimirovna and Dyachenko.*
>
> *The problem to which the present invention is directed is to recirculate spent gas from a medical device in a manner that ensures that the feed to the medical device is maintained at constant pressure and constant composition. In its broadest aspect (as defined in Claim 16), the solution is to divide the recirculatory circuit into higher and lower pressure sections, to maintain the gas composition by replenishing components and to take the feed to the medical device from the higher pressure section and to return the spent gas to the lower pressure section. None of the cited references is directed to this problem. In particular Lampotang et al is concerned with a ventilator and/or anaesthesia delivery system that relies upon pressure variation at a location in the recirculatory circuit to alternately provide and remove a gas mixture from a patient's lung.*
>
> *In order to derive the present invention from Lampotang et al, it is necessary for the skilled person to first make the decision that the teaching of Lampotang et al could have any relevance to provision of gas to a medical device at a constant pressure. It is an essential feature of Lampotang et al that variations in pressure in the*

recirculatory circuit should provide the motive force to provide ventilation to a patient and there is no teaching in Lampotang et al that the circuit might be used for any other purpose. If the skilled person did decide to modify Lampotang et alto provide a constant pressure at the feed location (14) to the endotracheal tube (16) (arguendo), there is no reason to believe that it would be considered necessary to retain either the flow control valve (132) or the bellows (218), because both of these components are present in order to facilitate the flowrate waveform required for patient ventilation.

With particular reference to the rejection of Claim 2 as being obvious over Lampotang et al in view of Simians, the differences between Lampotang et al and the present invention are so substantial that it is apparent that no combination with the teaching of Siemens could have led the skilled person to devise the apparatus of Claim 2 from the disclosure of Lampotang et al. The apparatus for that claim incorporates all of the features of Claim 1 and additionally the requirement that the feed gas supply inlets are located in the higher pressure section. Regardless of whether or not it was known in the art that feed gas supply inlets are located in the higher pressure section of a dual pressure main gas circuit, the apparatus Claim 1 would remain inventive over the prior art because of the combination of features required by that claim. **(Please note the feature of Claim 2 is now incorporated into amended Claim 1.)**

With particular reference to the rejection of Claim 9 as being obvious over Lampotang et al in view of Dyachenko, the fact that it was known to use ultrasonics to detect changes in gas composition does not render Claim 3 obvious because, as in the case of Claim 2, it incorporates the novel and inventive combination of the apparatus of Claim 1.

With particular reference to the rejection of Claims 12 and 13 as being obvious over Lampotang in view of Vladimirovna, there is no reason for the teaching of Vladimirovna to be combined with that of Lampotang et al. Vladimirovna is not concerned with ventilation and/or anaesthesia delivery but merely with the provision of a breathing mixture to a face mask. There may be individual features of Vladimirovna that might possibly be incorporated into the system of Lampotang but

they would not directly concern the recirculatory circuit because of the essential requirement of Lampotang et al that there is pressure variation to provide feed to and discharge from the endotracheal tube (16).

In connection with Vladimirovna, it should be noted that it appears that the recirculatory circuit in Vladimirovna does not have the high pressure and low pressure section required by the present claims and that the pressure in the recirculatory circuit at which the fresh gas is removed for feeding to the face mask is substantially the same as that at which the spent gas is returned from the face mask. The valve (26) between the feed and return locations is merely a one-way valve to prevent back flow of spent gas.

Allowable Subject Matter

The Examiner is thanked for advising that Claims 10, 11, 14 and 24 would be allowable if rewritten in independent form. However, the Applicants believe that, for reasons explained above, it is not necessary to restrict the application to the subject matter of these claims in order to meet the requirements of 35 USC § 102 & 103.

Summary

In view of the remarks above, the Applicant request that the objections set forth in the Office Action mailed on 2 September 2010 should be reconsidered and withdrawn. A timely Notice of Allowance is requested for the amended claims.

Respectfully submitted,

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